In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 16-759V

Filed: June 19, 2019

JESSICA BARRETT,	*	UNPUBLISHED
Petitioner,	*	
v.	*	Finding of Facts; Ruling on Onset; Influenza ("Flu") Vaccine; Shoulder Injury; Six-Month Requirement
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Paul Brazil, Esq., Muller Brazil, LLP, Dresher, PA, for petitioner.
Glenn MacLeod, Esq., U.S. Department of Justice, Washington, DC, for respondent.

FINDING OF FACTS AND RULING ON ONSET[1]

Roth, Special Master:

On June 28, 2016, Jessica Barrett ("Ms. Barrett" or "petitioner") filed a timely petition pursuant to the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10, *et seq.*[2] ("Vaccine Act" or "the Program"). Petitioner alleged that she received an influenza ("flu") vaccine on September 30, 2013, and "immediately following vaccination," felt "severe pain in her right shoulder." *See* Petition ("Pet.") at ¶¶2, 4. Petitioner claims her right shoulder injury lasted more than six months and was caused by the flu vaccination. *Id.* at ¶¶13-14.

[1] Although this Ruling has been formally designated "unpublished," it will nevertheless be posted on the Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (codified as amended at 44 U.S.C. § 3501 note (2006)). **This means the Ruling will be available to anyone with access to the internet.** However, the parties may object to the Ruling's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the whole Ruling will be available to the public. *Id.*

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (1986). Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

I. Background

A. Procedural History

On June 28, 2016, petitioner filed her petition along with her affidavit, medical records, an exhibit list, and a Statement of Completion. *See* Pet., Petitioner's Exhibits ("Pet. Ex.") 1-5, ECF Nos. 1, 3, 5. Petitioner did not file proof of vaccination.

This matter was initially assigned to the Special Processing Unit ("SPU") and handled by the chief special master. ECF Nos. 6-7.

On June 29, 2016, petitioner filed a Motion for Authority to Issue a Subpoena to the Hazleton Area School District for any records pertaining to petitioner, including her medical, vaccination, and employment records from September 1, 2010 to present. *Id*. at 1-2, ECF No. 9. This motion was granted. *See* Order, ECF No. 10.

The initial status conference was held on August 3, 2016. Petitioner's counsel acknowledged that proof of vaccination needed to be obtained and reported that a subpoena had been served on the Hazleton Area School District ("HASD"), where petitioner is employed in the Human Resources Department. Scheduling Order at 1, ECF No. 12. Petitioner was ordered to file outstanding vaccine records from HASD and an amended statement of completion. *Id*. Respondent was ordered to file a status report advising of his position within 30 days of petitioner filing an amended statement of completion. *Id*. at 1-2.

On September 2, 2016, petitioner filed HASD's response to the subpoena as Pet. Ex. 6. ECF No. 14. Petitioner also filed a status report ("Pet. S.R.") advising that the subpoena response did not contain petitioner's vaccination record. Pet. S.R. at 1, ECF No. 15. Petitioner requested an additional 45 days "to investigate whether fact witnesses could testify regarding vaccine administration." *Id*. Petitioner was ordered to file medical records or additional evidence by October 17, 2016. *See* Order, ECF No. 16.

On October 17, 2016, petitioner filed a status report ("Pet. S.R.") requesting a status conference to discuss documentation of petitioner's vaccination. Pet. S.R. at 1, ECF No. 17. A status conference was held on October 28, 2016, during which petitioner's counsel advised that petitioner's personnel file did not contain a record of the allegedly causal vaccination. Scheduling Order at 1, ECF No. 18. Additionally, the nurse who administered the vaccination had retired and could not be contacted. *Id*. Petitioner's counsel made an oral motion for a subpoena. *Id*. Petitioner was ordered to file any additional evidence by November 30, 2016. *Id*. An order was issued granting petitioner's oral motion for a subpoena. ECF No. 19.

On November 30, 2016, petitioner filed a status report ("Pet. S.R.") advising that she had been unable to obtain any additional documentation of her receipt of the flu vaccination. Pet. S.R. at 1, ECF No. 20. Petitioner proposed filing a status report in 45 days advising "whether additional evidence regarding vaccine administration is available, and if not proposing steps to advance the litigation." *Id.*

A status conference was held on December 20, 2016 to discuss "petitioner's difficulties with obtaining proof of vaccination." Scheduling Order at 1, ECF No. 21. Due to the lack of cooperation from HASD regarding document production, the Court recommended "seeking deposition testimony from relevant personnel." *Id*. Petitioner was ordered to file motions for subpoenas for deposition and production of relevant documents for specific HASD personnel by January 31, 2017. *Id*.

On January 31, 2017, petitioner filed her vaccine administration consent form as Pet. Ex. 7 along with a status report requesting a status conference to discuss further proceedings. ECF Nos. 22-23.

A status conference was held on February 14, 2017, to discuss the vaccine administration consent form filed as Pet. Ex. 7. Scheduling Order at 1, ECF No. 24. During the conference, petitioner's counsel advised that this form was located by petitioner and not provided by HASD. *Id*. Respondent's counsel advised that respondent did not believe this form was sufficient proof of vaccination. *Id*. Counsel for both parties advised the Court of "the myriad attempts and avenues …investigated to obtain proof of petitioner's vaccination." *Id*. Counsel further advised that HASD had not been cooperative in providing proof of vaccination. *Id*. Petitioner was ordered to submit an affidavit authenticating the consent form and including, among other items, "an explanation setting forth the date and circumstances regarding how the Consent Form was located." *Id*. at 1-2. Petitioner's counsel was ordered to submit an affidavit setting forth the date the subpoena was served on HASD, describing HASD's response to the subpoena, and confirming that no documents were produced in response to the subpoena. *Id*. at 2. The parties were ordered to file "a joint status report stating that all relevant evidence has been submitted…and stating whether the parties desire a fact ruling." *Id*.

On February 23, 2017, petitioner filed an affidavit stating that she works in the Human Resources Department for HASD, which offers the flu shot to all employees. Pet. Ex. 8 at 1, ECF No. 26. Petitioner affirmed that every year, an email is sent to employees indicating which dates the flu shot will be available. *Id*. In 2013, the flu shot administration date was September 27, with September 30 as a "make-up" day. *Id*. Petitioner affirmed that, on September 30, 2013, she waited in line with 15 to 20 other employees but did not recall the names of those employees. *Id*. at 2. Petitioner affirmed that, while waiting in line, she completed and signed a consent form; she then went to the office next door and made a copy. *Id*. Petitioner affirmed that it is her "general practice" to copy forms she is asked to sign. *Id*. When she received the flu shot, she turned in her consent form to the nurse who administered the shot but kept her copy of the form with her tax documents. *Id*. Petitioner was unable to produce any documentation of her flu vaccination other than the consent form.[3]

On March 16, 2017, petitioner filed an affidavit from counsel stating that counsel served a subpoena on HASD on July 18, 2016. In response, HASD produced several documents but failed to produce any documentation related to petitioner's 2013 vaccine. Pet. Ex. 9 at 1-2, ECF No. 27.

[3] Petitioner provided no explanation for how she remembered these details, upon what she relied for these details, or how, if this was a yearly event, she could recall these details as occurring in 2013 rather than another year.

Despite petitioner's representation that the school nurse was provided with, and retained, the original consent form, it too was apparently not included in HASD's response to the subpoena. Petitioner also filed a joint status report ("J.S.R.") requesting that the Court issue a fact ruling regarding vaccine administration, specifically "whether Petitioner received an influenza vaccination in her right shoulder on September 30, 2013." J.S.R. at 1, ECF. No. 28.

On June 2, 2017, without a hearing, a Fact Ruling was issued finding, by a preponderance of the evidence, that petitioner received a flu shot on September 30, 2013, in her right shoulder for the reasons set forth therein by the Chief Special Master. Fact Ruling at 2, ECF No. 29.

Respondent filed a status report ("Resp. S.R.") on July 3, 2017, requesting that petitioner file "any prior medical records pertaining to petitioner's orthopedic, neurology, and/or any musculoskeletal or physical therapy history." Resp. S.R. at 1, ECF No. 30. Petitioner was ordered to file these records and a status report by August 2, 2017. Scheduling Order at 1, ECF No. 31. Petitioner filed a status report ("Pet. S.R.") on August 2, 2017, advising that the records requested by respondent did not exist and that petitioner had submitted a settlement demand to respondent. Pet. S.R. at 1, ECF No. 32. Respondent was ordered to file a status report by September 5, 2017, advising whether he was willing to engage in settlement discussions. Scheduling Order at 1, ECF No. 33.

Respondent filed a status report ("Resp. S.R.") on September 5, 2017, advising that he was not amenable to settlement and requesting a deadline to file his Rule 4(c) Report. Resp. S.R. at 1, ECF No. 34. Respondent was ordered to file his Rule 4(c) Report by November 6, 2017. Non-PDF Order, dated Sept. 6, 2017.

Respondent filed his Rule 4(c) Report ("Resp. Rpt.") on November 6, 2017, recommending against compensation. ECF No. 35. Respondent submitted that petitioner's alleged injury did not meet the criteria for an on-Table SIRVA claim. *Id*. at 5. Respondent further submitted that petitioner did not complain of shoulder pain during a visit with her orthopedist on November 1, 2013, one month after receiving the flu shot, and in fact did not complain of shoulder pain until two months after receiving the flu shot. *Id*. at 6.

This matter was reassigned to me on November 28, 2017. ECF Nos. 36-37.

A status conference was held on January 17, 2018. Following a discussion of petitioner's medical history, I noted that petitioner's personnel records stated that she had right wrist surgery in September of 2014, but records reflecting this had not been filed. Scheduling Order at 1-2, ECF No. 38. Petitioner was ordered to file any and all records relating to her right wrist surgery by March 19, 2018. *Id*. at 2.

Petitioner filed an unopposed Motion for Extension of Time until April 18, 2018, to file her medical records. ECF No. 39. This motion was granted, and the deadline was extended to April 23, 2018. Non-PDF Order, dated Mar. 19, 2018.

Petitioner filed additional medical records on April 20, 2018. Pet. Ex. 10, ECF No. 40. Petitioner filed a Statement of Completion on April 24, 2018. ECF No. 41.

During a status conference held on June 5, 2018, I pointed out that the medical records filed did not support a sudden onset of shoulder pain as stated in petitioner's affidavit and the Petition, but rather an onset of shoulder pain two months after her flu vaccine. Scheduling Order at 1, ECF No. 42. Additionally, it was noted that the medical records did not support that petitioner suffered from her alleged injury for more than six months. *Id*. Petitioner's counsel requested the opportunity to file an expert report; I noted that, because there was a dispute as to onset, it was not yet appropriate to obtain an expert because the issue of onset needed to be addressed first. *Id*. at 2. Petitioner's counsel did not request an onset hearing to address the onset issue. I suggested that petitioner's counsel reach out to petitioner's treating physician to see if he recalled any information beyond what was contained in the medical records. *Id*. Petitioner was ordered to file a status report advising how she intended to remedy the inconsistencies between her affidavit and the medical records, and, if possible, an affidavit from her treating physician by August 6, 2018. *Id*.

Petitioner filed a status report on August 6, 2018, advising that "Petitioner and petitioner's counsel have been unable to engage in any communication with Dr. Jacobs and it is increasingly unlikely any communication will occur." Pet. S.R. at 1, ECF No. 43. Petitioner requested an additional 14 days to determine how she intended to proceed. *Id*. Petitioner was ordered to file a status report by August 21, 2018, indicating how she would like to proceed. Non-PDF Order, dated Aug. 7, 2018.

Petitioner filed a status report on August 21, 2018, advising that she was "still considering her options" and requesting an additional 14 days to determine how she intended to proceed. Pet. S.R. at 1, ECF No. 44. Petitioner's deadline to file a status report advising how she intended to proceed was extended to September 4, 2018. Non-PDF Order, dated Aug. 21, 2018.

Rather than requesting a hearing to determine onset or providing any additional evidence to corroborate her affidavit, petitioner filed a "Motion for Fact Ruling on the Record" on September 4, 2018, requesting a "fact ruling determining that Petitioner has provided evidence that satisfies her burden of proof, establishing that she suffered right shoulder injuries as a result of receiving the influenza ("flu") vaccine on September 30, 2013, and is therefore entitled to compensation." Motion for Fact Ruling on the Record ("MFRR") at 1,[4] ECF No. 45.

Respondent filed a response to petitioner's motion on September 17, 2018, submitting that petitioner had not proven by preponderant evidence that her symptoms began within 48 hours of vaccination, and that petitioner had not satisfied the six-month severity requirement. Response at 6-7, ECF No. 46.

Because petitioner requested an opportunity to provide an expert report but was not permitted to do so because the onset of her injury was in dispute, petitioner's Motion is being treated as a Motion for a fact ruling determining the onset of petitioner's alleged injury and whether petitioner has met the six-month severity requirement.

[4] Citations to petitioner's MFRR use the ECF designated page numbers rather than the page numbers as labeled by petitioner's counsel because those numbers are incorrect.

B. Petitioner's Medical History

Prior to her receipt of the allegedly causal flu vaccine, petitioner had a history of problems with her neck, right wrist, and back. On August 11, 2011, she presented to her primary care physician, Dr. Jacobs, complaining of a muscle spasm on the right side of her neck. Pet. Ex. 2 at 27. Petitioner was diagnosed with moderate right trapezius[5] spasm with tenderness and right paracervical spasm; she was prescribed tizanidine,[6] diazepam,[7] and physical therapy three times per week for four weeks. *Id*. Petitioner returned a month later, on September 12, 2011, because the spasm had not gone away. *Id*. at 34. She reported that physical therapy did not help, and she could not tolerate tizanidine. *Id*. She was diagnosed with right medial focal trapezius spasm with moderate tenderness and was referred for right trigger point injections. *Id*. An x-ray of her cervical spine showed moderate disc degeneration at C5-6 and straightening of normal cervical lordosis consistent with muscle spasm. *Id*. at 39. She returned again on October 11, 2011, still complaining of neck pain. *Id*. at 44. On exam, she had right paracervical spasm with tenderness, right trapezius tenderness, right sciatic notch tenderness, and a limited range of motion when she turned her head to the left. *Id*. She was diagnosed with cervicalgia[8] and sciatica,[9] both on the right side. *Id*. An MRI of the spine was ordered. *Id*. An MRI of the lumbar spine showed moderate sized posterior central disc extrusion at L5-S1. *Id*. at 49. An MRI of the thoracic spine was normal. *Id*. at 50. Petitioner returned on November 29, 2011, complaining that the left side of her neck was sore and stiff following a car accident. *Id*. at 53. On exam, she had tenderness on the left side of her neck, paracervical spasm, a limited range of motion on the left side of her neck, and left trapezius spasm. *Id*. She was diagnosed with cervicalgia and was prescribed prednisone and Flexeril.[10]

On August 29, 2012, petitioner presented to Dr. Jacobs for pain in the extensor tendon of her right thumb which radiated up her forearm, numbness and tingling in her fingers, and wrist pain; she was diagnosed with right tenosynovitis of the thumb. Pet. Ex. 2 at 59. Petitioner was advised to wear a thumb splint for 10 days, take ibuprofen, and avoid repetitive movements with her thumb. *Id*.

On February 20, 2013, petitioner presented to Dr. Battista at Orthopedic Associates of

---

[5] The trapezius muscle reaches from the seventh cervical vertebra to the clavicle and shoulder joint. It is used in raising the shoulder. *Musculus trapezius*, DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 1212 (32d ed. 2012) [hereinafter "DORLAND'S"].

[6] Tizanidine is a short-acting drug used to manage muscle spasms. *Tizanidine hydrochloride*, DORLAND'S at 1932.

[7] Diazepam is a benzodiazepine primarily used as an anti-anxiety agent; it is also used as a skeletal muscle relaxant. *Diazepam*, DORLAND'S at 512.

[8] Cervicalgia is neck pain. "Cervical" means pertaining to the neck. *Cervical*, DORLAND'S at 333. "-algia" is a word termination denoting a painful condition. *-algia*, DORLAND'S at 48.

[9] Sciatica is a syndrome characterized by pain radiating from the back into the buttock. *Sciatica*, DORLAND'S at 1678.

[10] Flexeril is the brand name for cyclobenzaprine hydrochloride, a drug used as a skeletal muscle relaxant for relief of painful muscle spasms. *Flexeril*, DORLAND'S at 717; *cyclobenzaprine hydrochloride*, DORLAND'S at 455.

Allentown ("OAA") for tenosynovitis of the right hand and wrist. Pet. Ex. 4 at 40-41. She was administered betamethasone[11] and lidocaine[12] injections. *Id.* at 63.

Petitioner returned to Dr. Battista on August 23, 2013, for follow-up of radial styloid tenosynovitis[13] in her right wrist. Pet. Ex. 4 at 39, 62. She was prescribed methylprednisolone. *Id*. at 62.

In her affidavit, petitioner agreed that she had a history of right wrist problems but stated that her symptoms never included shoulder pain. Pet. Ex. 1 at 2. Petitioner further stated that, prior to her vaccination, she had never injured her right shoulder. *Id*.

Petitioner received the allegedly causal flu vaccine on September 30, 2013, at her place of employment, the office of Hazleton School District. Pet. Ex. 1 at 1; Pet. Ex. 8 at 1-2; Fact Ruling at 2. Petitioner stated in her affidavit that "within hours" of her vaccination, her "right arm and shoulder became very painful." Pet. Ex. 1 at 1. According to petitioner, "The pain progressed over the following weeks" before she elected to seek medical attention from her primary care physician on November 29, 2013. *Id*.

Approximately one month later, on November 1, 2013, petitioner presented to Dr. Battista for follow-up of her right radial styloid tenosynovitis. Pet. Ex. 4 at 96. Petitioner reported little change in her symptoms since her last visit; the splint was helpful for nighttime, but she had trouble wearing it during the day. *Id*. She reported weakness, swelling, and stiffness in her right wrist, as well as dry eyes and sinus pressure. *Id*. at 97, 98. Upon exam, she had tenderness of the radial styloid and swelling of the first dorsal extensor sheath. *Id*. at 99. She received lidocaine and betamethasone injections in her right wrist and was instructed to follow-up in two months. *Id*. at 68, 99. Petitioner made no complaints to Dr. Battista at this visit or during his examination of any right arm or shoulder pain.

On November 13, 2013, petitioner was discharged from physical therapy for her right wrist because she was unable to get time off from work for the therapy. Pet. Ex. 4 at 46. This record did not document petitioner making any complaints of right shoulder pain.

On November 29, 2013, petitioner presented to Dr. Jacobs complaining of a scab in her right nostril for the past six months as well as tendonitis[14] in her right wrist. Pet. Ex. 2 at 66. Upon

---

[11] Betamethasone is a steroid used as an anti-inflammatory and immunosuppressant. *Betamethasone*, DORLAND'S at 211.

[12] Lidocaine is a local anesthetic applied topically to the skin or via infiltration injection. *Lidocaine*, DORLAND'S at 1034.

[13] Radial styloid tenosynovitis is inflammation of a tendon sheath near the radius, one of the bones of the forearm. *Radial*, DORLAND'S at 1570; *radius*, DORLAND'S at 1574; *tenosynovitis*, DORLAND'S at 1882. Radial styloid tenosynovitis is also known as de Quervain disease, an "overuse injury with painful tenosynovitis due to relative narrowness of the common tendon sheath" of muscles in the thumb. *De Quervain disease*, DORLAND'S at 532; *musculus abductor pollicis longus*, DORLAND'S at 1203; *musculus extensor pollicis brevis*, DORLAND'S at 1204.

[14] Tendinitis is inflammation of tendons and of tendon-muscle attachments. *Tendinitis*, DORLAND'S at 1881.

exam, she had marked tenderness over her right trapezius and could not "abduct past 90 degrees w/o severe pain." *Id*. at 67. Her left side was "not as bad." *Id*. The assessment was bilateral shoulder tendinitis. *Id*. at 67-68. MRI without contrast of both shoulders was ordered. *Id*. at. 68. She was prescribed prednisone. *Id*. at 70. Petitioner did not mention the flu vaccine when reporting bilateral shoulder pain.

MRIs of the left and right shoulders were performed on December 12, 2013, showing "Tendinosis of the rotator cuff tendons" in both shoulders. Pet. Ex. 2 at 92; Pet. Ex. 4 at 74. Petitioner had mild acromioclavicular degeneration of her right shoulder. Pet. Ex. 3 at 1; Pet. Ex. 4 at 75.

Petitioner next presented for care on January 14, 2014, to Dr. Jacobs complaining of right shoulder pain. Pet. Ex. 2 at 101. Her exam was normal. *Id*. at 102. Petitioner was diagnosed with insomnia, for which she was prescribed zolpidem tartrate;[15] allergic rhinitis, for which she was prescribed cetirizine;[16] and tendinitis of the right rotator cuff, for which no treatment was rendered. *Id*. at 107. Petitioner was instructed to return in six months. *Id*. at 105.

Two days later, on January 21, 2014, petitioner presented to Dr. Hawkins at OAA, complaining of right shoulder pain. Pet. Ex. 4 at 92. Petitioner reported that she began having right lateral arm pain about a month after receiving a flu shot. *Id*. The pain was especially bad at night and she did not have relief with Ambien. *Id*. She denied numbness or neck pain. *Id*. Upon exam, she had tenderness of the rotator cuff and was positive for lateral impingement, Hawkins test, and Neer test. *Id*. at 95. An MRI showed an intact rotator cuff without glenohumeral effusion and "very mild" subacromial bursitis. *Id*. The assessment was right shoulder pain with impingement[17] and possible rotator cuff tendonitis.[18] *Id*. She was administered lidocaine and Depo-Medrol[19] injections in her right shoulder and referred to physical therapy for right shoulder impingement. *Id*. at 32, 67, 95.

On January 23, 2014, petitioner presented to Dr. Plaza for an initial physical therapy evaluation. Pet. Ex. 5 at 4. She reported an onset of right shoulder pain around mid-October of 2013, or two weeks after a flu shot. *Id*. The pain was waking her up at night and she was having

[15] Zolpidem tartrate is a non-benzodiazepine sedative-hypnotic administered orally in the short-term treatment of insomnia. *Zolpidem tartrate*, DORLAND'S at 2092.

[16] Cetirizine hydrochloride is a non-sedating antihistamine used in the treatment of allergic rhinitis. *Cetirizine hydrochloride*, DORLAND'S at 334.

[17] Impingement syndrome is a type of overuse injury with progressive pathologic changes resulting from mechanical impingement by a ligament or joint against the rotator cuff. *Impingement syndrome*, DORLAND'S at 1834.

[18] Rotator cuff tendinitis, is an overuse injury consistent of inflammation of tendons of one or more of the muscle forming the rotator cuff, usually owning to repetitive elevation and abduction of the upper limb. *Tendinitis*, DORLAND'S at 1881.

[19] Depo-Medrol is the brand name for methylprednisolone acetate, a steroid administered topically or by injection as an anti-inflammatory and immunosuppressant. *Depo-Medrol*, DORLAND'S at 492; *methylprednisolone*, DORLAND'S at 1154.

occasional paresthesias in her right hand. *Id*. Upon exam, she was positive on the Hawkins-Kennedy test, the Neer test, and the "empty can" test. *Id*. She had a negative Yergason's test. *Id*. She had moderate tenderness around the anterior shoulder/lateral deltoid area. *Id*. at 5. It was noted that petitioner tolerated treatment well and had some relief. *Id*. It was noted that she would benefit from physical therapy to decrease her right shoulder pain with functional activity and return to her pre-injury level of function. *Id*. Dr. Plaza recommended physical therapy three times per week for four weeks, for a total of twelve visits. *Id*. at 6.

Petitioner returned for physical therapy on February 10, 2014 and February 24, 2014. Pet. Ex. 5 at 7-10.

On April 25, 2014, petitioner presented to Dr. Hawkins complaining of a right shoulder problem. Pet. Ex. 4 at 90. She had received a right subacromial injection in January and started physical therapy with notable improvement; her shoulder issues had not resolved but were "much better." *Id*. She had some pain but was functional for all work and "ADLs." *Id*. Upon exam, she did not have tenderness at the acromioclavicular joint, but had mild pain with active abduction. *Id*. at 91. The assessment was mild persistent right shoulder pain with a history of mild bursitis by MRI. *Id*. at 92. Her symptoms did not warrant operative intervention; she was instructed to follow-up as needed. *Id*. That day, she also received lidocaine and betamethasone injections in her right wrist. *Id*. at 66, 89.[20]

Three months later, on July 11, 2014, petitioner presented to Dr. Culp at Philadelphia Hand to Shoulder Center, complaining of right wrist pain for longer than a year, despite having a normal MRI. Pet. Ex. 10 at 12. Upon exam, she was noted to have "full range of motion of the shoulders without tenderness." *Id*. She was diagnosed with "right intersection syndrome" and was determined to be a candidate for surgical release of the right wrist. *Id*. at 13. Petitioner did not complain of right shoulder pain at this visit.

On October 24, 2014, petitioner underwent right intersection release on her right wrist, a surgical procedure performed under anesthesia. Pet. Ex. 10 at 17-18. Petitioner returned to Dr. Culp for subsequent follow-up visits on November 7 and December 12, 2014. *Id*. at 10-11.

Petitioner's next visit to any medical professional with right shoulder pain was on February 27, 2015, when she presented to Dr. Hawkins. Pet. Ex. 4 at 85. She reported muscle aches, muscle weakness, and arthralgias and joint pain. *Id*. at 87. She had tenderness of the right rotator cuff but full range of motion. *Id*. at 88. An MRI showed no fracture or dislocation with well-preserved joint spaces and normal alignment. *Id*. The assessment was mild recurrent right shoulder pain with a history of mild subacromial bursitis. *Id*. She was administered lidocaine and Depo-Medrol injections. *Id*. at 65, 88. She was encouraged to continue with home exercises and stretches. *Id*. at 89.

Two years later, on April 13, 2017, petitioner was again referred to Dr. Culp, who she presented to on April 13, 2017 with a chief complaint of right elbow pain. Pet. Ex. 10 at 8.

[20] No records were filed indicating that petitioner presented for any further physical therapy for her right shoulder other than the two visits in February of 2014.

Petitioner reported that, in February of 2016, she hit her elbow on the corner of an island at home, resulting in severe pain. *Id*. Another doctor had diagnosed her with medial epicondylitis;[21] home physical therapy was recommended. *Id*. She was taking Triamterene (diuretic) and Restasis (dry eyes). *Id*. Upon exam, she had "full range of motion of both shoulders without tenderness" and tenderness over the medial epicondyle. *Id*. at 9. The impression was right medial epicondylitis[22] and right medial collateral ligament rupture of the right elbow. *Id*. Dr. Culp recommended another MRI. *Id*.

An MRI of petitioner's right elbow performed on October 10, 2016, showed a cyst on her elbow. The differential diagnosis included synovial cyst or ganglion cyst. Pet. Ex. 10 at 23.

Petitioner returned to Dr. Culp on April 18, 2017, for right medial elbow pain. Pet. Ex. 10 at 7. Dr. Culp noted that petitioner's MRI was consistent with medial epicondylitis. *Id*. Several treatment options were discussed, including bracing, therapy, injections, and surgery. *Id*. Petitioner requested a platelet rich plasma ("PRP") injection. *Id*.

The remainder of the medical records provided are for treatment of petitioner's elbow. There were no further shoulder complaints in the records.

III. Applicable Legal Standards

A. Legal Standards Regarding Fact Finding

Petitioner bears the burden of establishing her claims by a preponderance of the evidence. § 13(a)(1). A petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he or she] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted).

The process for making determinations in Vaccine Program cases regarding factual issues, such as the timing of onset of petitioner's alleged injury, begins with analyzing the medical records, which are required to be filed with the petition. § 11(c)(2). Medical records created contemporaneously with the events they describe are presumed to be accurate and "complete" such that they present all relevant information on a patient's health problems. *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). This presumption is based on the linked proposition that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in an accurate manner, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Human Servs*.,

[21] No records of this medical visit or treatment were filed. It appears that not all of petitioner's medical records were filed in this matter.

[22] Medical epicondylitis is an overuse injury with pain around the medial epicondyle of the humerus where the flexor muscles of the arm and hand attach, popularly called "golfer's elbow." *Epicondylitis*, DORLAND'S at 630.

No. 11-685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Human Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd,* 993 F. 2d. 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms. It is equally unlikely that pediatric neurologists, who are trained in taking medical histories concerning the onset of neurologically significant symptoms, would consistently but erroneously report the onset of seizures a week after they in fact occurred"). In making contemporaneous reports, "accuracy has an extra premium" given that the "proper treatment hang[s] in the balance." *Id.* A patient's motivation for providing an accurate recount of symptoms is more immediate, as opposed to testimony offered after the events in question, which is considered inherently less reliable. *Reusser v. Sec'y of Health & Human Servs*., 28 Fed. Cl. 516, 523 (1993); *see Murphy v. Sec'y of Health & Human Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd*, 968 F.2d 1226 (Fed. Cir. 1992) (citing *United States v. U.S. Gypsum Co.*, 333 U.S. 364, 396 (1948)). Contemporaneous medical records that are clear, consistent, and complete warrant substantial weight "as trustworthy evidence." *Cucuras*, 993 F.2d at 1528. Indeed, "where later testimony conflicts with earlier contemporaneous documents, courts generally give the contemporaneous documentation more weight." *Id.* Similarly, contemporaneous medical records may be considered more persuasive than a petitioner's affidavit created years after the fact. *See Gerami v. Sec'y of Health & Human Servs.*, No. 12-442V, 2013 WL 5998109, at *4 (Fed. Cl. Spec. Mstr. Oct. 11, 2013), *mot. for rev. denied*, 127 Fed. Cl. 299 (2014) (finding that contemporaneously documented medical evidence was more persuasive than the letter prepared for litigation purposes).

B. Determination of Onset

The onset of petitioner's alleged shoulder injury is documented as a month or two weeks after the allegedly causal flu vaccine. Petitioner affirmed that she began to experience pain in her right shoulder within hours of receiving a flu vaccination on September 30, 2013, and that the pain progressed over the following weeks. Pet. Ex. 1 at 1.

However, despite petitioner's affirmation that her shoulder pain began within hours of receiving the flu vaccine, she did not present for any medical care related to her shoulder in the weeks following the vaccination. On November 1, 2013, petitioner presented to her orthopedist complaining only of pain in her right wrist. Pet. Ex. 4 at 96-98. Petitioner did not complain of right shoulder pain at this visit. A physical exam conducted on this date noted problems with only her right wrist, not her right arm or shoulder. *Id*.

Petitioner's first documented complaint of shoulder pain was on November 29, 2013, during an appointment with her primary care provider for a scab in her nose and follow-up of right wrist pain. At that time, she complained of bilateral shoulder pain; MRIs were ordered for both shoulders and showed bilateral tendinosis of the rotator cuff tendons with mild acromioclavicular degeneration in the right shoulder. Pet. Ex. 2 at 66-68, 92; Pet. Ex. 3 at 1. In making the complaint of bilateral shoulder pain, petitioner did not advise her physician of how long she had been having shoulder pain, of having received a flu vaccination, or that the onset of any pain occurred following the vaccine. At appointments on January 21 and January 23, 2014, when petitioner presented with complaints of right shoulder pain she then provided onset dates of approximately one-month post-vaccination and two weeks post-vaccination, respectively. Pet. Ex. 4 at 92; Pet. Ex. 5 at 4. Records

for other appointments of treatment for her right shoulder pain do not indicate when the pain began. *See* Pet. Ex. 2 at 66-68, 101.

Here, petitioner provided only her affidavit, created nearly three years after her receipt of the allegedly causal vaccination, to support an onset of symptoms "within hours" of her vaccination. Petitioner's affidavit provided little detail about the onset of her symptoms, but merely stated that it began within hours of vaccination and progressed over several weeks before she sought medical care. Pet. Ex. 1 at 1. This is insufficient to overcome the presumption of correctness afforded to contemporaneous medical records. The records reflect petitioner's report of onset as either two weeks, in mid-October, or one month after vaccination. The onset of shoulder pain on either of these dates would mean that petitioner was experiencing right shoulder pain when she presented to her orthopedist on November 1, 2013. It strains reason that, if petitioner had right shoulder pain at this time, she would fail to mention it during an appointment with her orthopedist for treatment of pain in her right wrist, particularly when that appointment involved a physical exam of her right arm. Based on the contemporaneous medical records, the most likely onset date for petitioner's right shoulder pain appears to be around November 29, 2013, when she reported an onset of bilateral shoulder pain to her primary care provider.

C. Six-Month Requirement

The Vaccine Act requires petitioners to show by preponderant evidence that the "residual effects or complications of [the alleged] illness, disability, injury, or condition for more than 6 months after the administration of the vaccine…." 42 U.S.C. § 300aa-11(c)(1)(D)(i). In *Cloer v. Sec'y of Health and Human Servs.*, the Federal Circuit explained that the six-month requirement is "a condition precedent for filing a petition for compensation" in the vaccine program and serves as a restriction on eligibility for compensation in the Program. 654 F.3d 1322, 1335 (Fed. Cir. 2011). Congress intended this duration requirement "to limit the availability of the compensation system to those individuals who are seriously injured from taking a vaccine." *Id.* (quoting H.R. Rep. No.100-391(I), at 699 (1987), *reprinted in* 1987 U.S.C.C.A.N. 2313-1, -373.

Respondent submitted that petitioner has not met the six-month requirement, based on respondent's calculation of a five-month period from onset of symptoms on November 29, 2013 until April 25, 2014, when petitioner presented to her orthopedist and was noted to have had "notable improvement." Response at 7. However, the plain language of the statute states that the vaccinee must suffer from the alleged injury for more than six months after the *administration* of the vaccine. Based on petitioner's vaccination date of September 30, 2013, petitioner need only demonstrate that she suffered from her alleged injury through March 30, 2014. When petitioner presented to her orthopedist on April 25, 2014, she reported that her shoulder problem had not resolved but was "much better." Pet. Ex. 4 at 90. On exam, she still had mild pain with active abduction. *Id.* at 91. The contemporaneous medical records indicate that petitioner was still complaining of shoulder pain more than six months after receiving the flu shot. Based on the foregoing, I find that petitioner complained of alleged shoulder pain in excess of a six-month period following the administration of the flu vaccine.

IV. Conclusion

Upon detailed review of the record, I find that petitioner's right shoulder pain began on or about November 29, 2013, and that petitioner has satisfied the six-month severity requirement. Petitioner has 90 days to file an expert report which relies on the facts as found in this Ruling and complies with the *Althen* criteria. Should petitioner's expert base his or her opinion on facts not substantiated by this Ruling, the expert's report will be disregarded. *See Burns by Burns v. Sec'y of Health & Human Servs*., 3 F.3d 415, 517 (Fed. Cir. 1993).

Accordingly, the following is ORDERED:

By Tuesday, September 17, 2019, petitioner shall file either an expert report that is based on the onset as found herein, or a status report indicating how she intends to proceed. Petitioner shall provide a copy of this Onset Ruling to each of her expert witnesses, and her expert(s) shall rely on the timing of onset as I have found it in this Ruling. If petitioner is unable to secure reports from her expert(s) based on the timing of onset as I have found it, she shall file either a motion to dismiss, a joint stipulation for dismissal, or a motion for a ruling on the record, all of which will result in the dismissal of her claim.

IT IS SO ORDERED.

s/ Mindy Michaels Roth
Mindy Michaels Roth
Special Master